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08/876,132	06/23/1997	TIMOTHY FOWLER	CG372	4697

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
08/876,132	FOWLER ET AL.	
Examiner	**Art Unit**	
Daniel M Sullivan	1636	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is a response to the "Amendment and Response" of 29 December 2003, filed in reply to the Non-Final Office Action mailed 23 September 2003. Claims 18-20 were withdrawn from consideration and claims 1-17 were considered in the 23 September Office Action. Claims 1-20 were canceled and new claims 21-38 were added in the 29 December Paper. Claims 21-38 are pending and under consideration.

Response to Amendment

Rejection of claims 1-17 is rendered moot by cancellation of the claims.

Drawings

Objection to the drawings is withdrawn in view of the filing of formal drawings.

New Grounds

Claim Objections

Claim 25 is objected to because of the following informalities: The accession number set forth in the claim is incorrect. The correct ATCC accession number is 39140 as set forth at page 7, line 19 of the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-25 and 27-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The MPEP states, "[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." (MPEP § 2163.06). The MPEP further states, "[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application" (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

The base claims 21, 29 and 33 limit the cryptic plasmid of the claims to at least 90% (claims 21 and 33) or 95% (claim 29) sequence identity with SEQ ID NO: 1 or SEQ ID NO: 2.

In the remarks, Applicant indicates that support for these limitations can be found in original claims 1, 2 and 5 and also at page 4 of the disclosure. However, the cryptic plasmid of original claims 1, 2 and 5 is not limited to comprising SEQ ID NO: 1 or SEQ ID NO: 2 at all. Although claim 6 limits the limits the plasmid to having the sequence of SEQ ID NO: 1 or SEQ ID NO: 2, there is no recitation of percent identity. The passage on page 4 cited by Applicant reads as follows, "[p]referred nucleic acid homologs or variants are those having at lest 80%, at least 90% and at least 95% identity to SEQ ID NO: 1 and SEQ ID NO: 2" (lines 17-18). Thus, the homologues contemplated in the specification, which must have at least 80%, at least 90% and at least 95% identity to both SEQ ID NO: 1 and SEQ ID NO: 2, are of considerably more narrow scope than the homologues recited in the new claims, which need only comprise 90% or 95% identity with either one of SEQ ID NO: 1 or SEQ ID NO: 2. Thus, the specific genera of plasmids to which the instant claims are now limited has no explicit or implicit support in the originally filed disclosure. Therefore claims contain new matter.

Claims 21-24, 26 and 29-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the previous Office Action it was indicated that, for the reasons set forth therein, the disclosure provides descriptive support only for the method wherein the progenitor strain is a *Pantoea citrea* strain comprising the cryptic plasmid pS, which comprises *both* SEQ ID NO: 1

and SEQ ID NO: 2 (see especially the paragraph bridging pages 8-9). In contrast, the newly filed claims encompass the method wherein the progenitor strain is any *Enterobacteriaceae* strain comprising a cryptic plasmid having 90% or 95% sequence identity with SEQ ID NO: 1 or SEQ ID NO: 2.

As stated in the previous Office Action, the instant disclosure provides a single example of a progenitor strain useful in the instant claimed method, which is not representative of the genus of any *Enterobacteriaceae* strain comprising a plasmid which alters the growth or mobilization characteristics of said *Enterobacteriaceae* such that when the plasmid is eliminated the growth characteristics are improved or the mobilization properties are reduced, and the specification fails to teach the relevant identifying characteristics of the *Enterobacteriaceae* strain of the claims. Although the progenitor strain is now limited to comprising a plasmid having some identity with SEQ ID NO: 1 or SEQ ID NO: 2, there is no evidence of record that the limitations recited in the claim correlate with a progenitor strain that can be used in the method. As discussed in the previous Office Action, the specification sets forth no structural limitations which are correlated with the functional limitations aside from the pS plasmid comprising both SEQ ID NO: 1 and SEQ ID NO: 2.

Response to arguments

In the Remarks, Applicant contends, "one skilled in the art, along with the teachings of the recent disclosure, could determine without undue experimentation whether or not an P Enterobacteriaceae strain and particularly a strain of a *Pantoea*, *Enterobacter*, *Erwinia* or *Gluconobacter*, comprise a plasmid having at least 90% sequence identity with the nucleic acid

sequence of pS and further whether or not elimination of the plasmid from the progenitor strain would produce an improved Enterobacteriaceae strain" (page 7).

This argument has been fully considered but is not deemed persuasive. First, it should be made clear that the plasmid of the claims is not limited to 90% sequencc identity with the nucleic acid sequence of pS, but to 90% sequence identity with one of the fragments of pS set forth as SEQ ID NO: 1 or SEQ ID NO: 2. Furthermore, Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115). As stated in the previous Office Action, an adequate written description of a plasmid requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the plasmid itself. It is not sufficient to define plasmid solely by its principal biological property (i.e., when deleted it alters the phenotypic growth characteristics or alters mobilization properties of other *Enterobacteriaceae* resident plasmids), because disclosure of no more than that, as in the instant casc, is simply a wish to know the identity of any plasmid, or progenitor strain comprising said plasmid, with that biological property.

Claims 21-24, 26 and 29-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for preparing an improved *Enterobacteriaceae* strain from a progenitor *Enterobacteriaceae* strain, wherein said progenitor *Enterobacteriaceae* strain comprises the cryptic plasmid pS, does not reasonably provide enablement for the mcthod wherein the progenitor *Enterobacteriaceae* comprises a cryptic plasmid other than pS. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

As indicated in the previous Office Action, and for reasons set forth therein, the specification fails to provide enablement for the claims beyond the scope of the method wherein the progenitor strain is an *Enterobacteriaceae* strain containing the cryptic plasmid pS and an improved *Enterobacteriaceae* made by the method.

Response to arguments

In the Remarks, Applicant contends, "one skilled in the art, along with the teachings of the resent disclosure, could determine without undue experimentation whether or not an P Enterobacteriaceae strain and particularly a strain of a *Pantoea*, *Enterobacter*, *Erwinia* or *Gluconobacter*, comprise a plasmid having at least 90% sequence identity with the nucleic acid sequence of pS and further whether or not elimination of the plasmid from the progenitor strain would produce an improved Enterobacteriaceae strain" (page 7).

This argument has been fully considered but is not deemed persuasive. Practicing the method of the claims still requires identification of progenitor strains comprising cryptic plasmids of highly divergent structure (*Id.*). As discussed in the previous Office Action, the instant specification provides a single example of an *Enterobacteriaceae* strain useful in the claimed method (i.e., *Pantoea citrea* comprising the 3.8 Kb pS plasmid), and teaches that the phenotype obtained upon elimination of the pS plasmid was unexpected. The disclosure is silent with regard to how to obtain other progenitor strains that could be used in the claimed method other than random trial and error experimentation. Although the relative level of skill in the art is

high, the skilled artisan would not be able to use the full scope of the claimed method without engaging in undue experimentation to isolate progenitor strains that could be used in the method. Given the unpredictability of phenotype obtained by eliminating any given plasmid from an *Enterobacteriaceae* strain and the absence of guidance in the art and instant disclosure that would enable the skilled artisan to identify strains useful in the claimed method, the skilled artisan would have to engage in blind trial and error experimentation to test each strain of *Enterobacteriaceae* comprising a plasmid having the broad structural features set forth in the claims to identify those strains useful in the method.

Claim 25 is additionally rejected under 35 U.S.C. 112, first paragraph, because the claims refers to biological deposits to satisfy the enablement requirement, but the disclosure does not indicate that a biological deposit was made according to the rules set forth for deposit of biological material (M.P.E.P. 2401-2411). This rejection was set forth against claims 7 and 15 in the previous Office Action. Applicant's reply does not address the grounds for rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27 is rejected under 35 U.S.C. 102(b) as being anticipated by either one of Sykora *et al.* (1989) *Plasmid* 21:85-98 (made of record in the previous Office Action) or Yoshikawa *et al.* (1967) *J. Bacteriol.* 93:245-253 (made of record in the previous Office Action).

The claim is directed to an *Enterobacteriaceae* strain made by a method wherein a cryptic plasmid is eliminated from a progenitor strain. As the claim is a product-by-process claim, it reads on an *Enterobacteriaceae* strain made by any means. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In the instant case, the claim reads on any *Enterobacteriaceae* strain that does not comprise a cryptic plasmid having the limitations of the plasmid of claim 21. Although the claimed *Enterobacteriaceae* strain is limited to having the ability to grow at higher temperatures than a progenitor strain comprising the plasmid, this property would presumably be inherent to any strain not comprising the cryptic plasmid.

Both Sykora *et al.* and Yoshikawa *et al.* teach an *E. coli* strain (see pages 13 and 14 of the previous Office Action). Absent evidence to the contrary, the *E. coli* strains taught by Sykora *et al.* and Yoshikawa *et al.* do not contain the cryptic plasmid according to the limitations of claim 21 and therefore read on the product of the method. As the *Enterobacteriaceae* strains taught by Sykora *et al.* and Yoshikawa *et al.* are the same as the product of claim 21, claim 27 is anticipated by Sykora *et al.* and Yoshikawa *et al.*

Claims 27, 28, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Sonoyama *et al.* (1987) US Patent No. 4,696,897 as evidenced by Bilic *et al.* (1997) *J. Appl. Microbiol.* 83:485-492 (made of record in the IDS filed 27 August 1998) and ATCC accession numbers 31626 and 31628.

The claims are directed to *Enterobacteriaceae* strain or *Pantoea* strain made by the method of claims 21 or 23. The claims are directed to a product by process and, as such, read on any *Enterobacteriaceae* or *Pantoea* strain that does not comprise the not contain the cryptic plasmid according to the limitations of claims 21 or 23 (*Id.*). Sonoyama *et al.* teaches *Erwinia* strains deposited as ATCC accession number 31626 and 31628 (see especially Table I). ATCC accession number 31626 and 31628 teach that these strains were reclassified as *Pantoea*.

Bilic *et al.* teaches that many cryptic plasmids have been isolated from different *Erwinia* strains ranging from 4.2-340 kb (paragraph bridging the left and right columns on page 485). Bilic *et al.* identifies a 3.8 kb (*i.e.*, the instant pS) plasmid in an *Erwinia* (*Pantoea*) *citrius* strain and teaches that the plasmid is one of the smallest plasmids isolated from the genus *Erwinia* (first paragraph of the "Discussion" on page 490). Thus, it would appear that the pS plasmid is not a universal feature of *Pantoea*. Given these teachings, the skilled artisan would think it more likely than not that the one or both of the *Pantoea* strains taught by Bilic *et al.* does not comprise the pS plasmid and therefore meets the limitations of the *Pantoea* strain of the instant claims. Absent evidence to the contrary, the *Pantoea* strains taught by Sonoyama *et al.* are the same as those claimed in the instant application, therefore the claims are anticipated by Sonoyama *et al.* as evidenced by Bilic *et al.* and the cited ATCC accession numbers.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27, 28, 37 and 38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish over *Enterobacteriaceae* strains as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Because the claims are directed to a product by process (*Id.*), they read on any *Enterobacteriaceae* or *Panotea* strain that does not contain the pS plasmid including those strains that occur naturally. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught by page [insert page number] of specification. See MPEP 2105.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

DAVID GUZO
PRIMARY EXAMINER